DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94981d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

WARNING LETTER

FLA-04-41

September 14, 2004

James L. Hanson, President
Hanson Seafood, Inc.
12950 West Dixie Highway
North Miami, Florida 33161

Dear Mr. Hanson:

On May 10-11 and 21, 2004, we inspected your seafood processing facility, located at the above address. We found that you have serious deviations from the Seafood HACCP Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and Current Good Manufacturing Practice Requirements for Food (GMP), 21 CFR Part 110. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your Scombrotoxin (histamine) forming fresh fish and refrigerated, canned pasteurized crabmeat are adulterated in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act and the Seafood HACCP Regulations through links in FDA's homepage at http:// www.fda.gov.

The deviations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b).

   However, your firm does not have a HACCP plan for refrigerated, canned pasteurized crab meat to control the food safety hazards of *Clostridium botulinum* growth/toxin formation and pathogen growth/toxin formation. Our investigator collected a document entitled "HACCP plan for pasteurized crabmeat" consisting of a hazard analysis and letter of guarantee. Your hazard analysis correctly lists "botulism" (i.e., *Clostridium botulinum*) as a potential food safety hazard reasonably likely to occur. Your hazard analysis uses sanitation standard operating procedures (SSOP's) as the method for

control of *Clostridium botulinum*. FDA does not consider the use of SSOP's an adequate control for this type of hazard and requires a HACCP plan with the appropriate critical control points necessary to ensure the safety of the product.

2. You must have a HACCP that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c) (4). However, your firm lists a monitoring frequency at the Chilled Storage critical control point that is not adequate to control histamine development in your HACCP Plan for Fresh Scombroid Species. You list that you will monitor the cooler temperature [redacted] a day, and re-ice inventory each day. For monitoring of ambient cooler temperatures, we recommend the use of a continuous monitoring device with a visual check of the instrument at least daily. When monitoring for the presence of ice, we recommend a visual check for adequacy of the ice surrounding the product performed on a representative number of containers at least twice daily.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective must be appropriate, to comply with 21 CFR 123.7(b). However, your HACCP plan for Fresh Scombroid Species lists corrective actions that are not appropriate at the Receiving and Chilled Storage critical control points. You list that if the critical limits are exceeded, the fish will be "evaluated" or "examined for decomposition". Appropriate corrective actions include evaluating time and temperature exposures, destroying the product, and/or conducting histamine testing on a representative number of samples.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751.

If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,

Emma R. Singleton
District Director
Florida District